

REMARKS

This amendment is responsive to the Office Action dated October 1, 2004, a response is due on January 1, 2005, without extension of the time for response.

Claims 1-4, 6-34, 71, and 72-104 are pending in the application. Claims 72-104 are new.

The Examiner has rejected claims 1-4, 6-34, and 71 under 35 U.S.C. § 112(1) for our introduction of the term “alternately” in amended claim 1. The Examiner construes this word to mean “to do in successive turns, to interchange, or rotate”. She correctly points out that, in view of this construction of “alternately”, the specification does not support this use of the word. Accordingly, Applicant further amends claim 1 to delete this word.

The Examiner has also rejected claims 1-4, 6-34, and 71 under 35 U.S.C. § 112(2) for failing to particularly point out and distinctly claim the invention. Specifically, the Examiner indicates that the term “selecting” infers a selection process, which is not defined in the specification. Therefore, Applicant amends Claim 1 to read “providing” rather than “selecting”.

Additionally, the Examiner rejected claims 1-4, 6-34, and 71 apparently under 35 U.S.C. § 112(2) contending that a product recovery step must be claimed in order to “particularly point out and distinctly claim the ‘complete’ process”. The Applicant respectfully points out that § 112(2) requires that he particularly point out and distinctly claim the invention, but not to so claim the entire disclosed process. Only part of the disclosed process is inventive, and only that part must be claimed. The heart of the present development lies in its inventive use of alternative oxidant sources, which is indeed included in claim 1. It is the use of such materials to produce a biological product, rather than the product itself, which is the invention. Thus an isolation step is not necessary. Accordingly, we have particularly pointed out and distinctly claimed the invention under § 112(2), and respectfully request the Examiner to withdraw her rejection.

Claims 1-4, 6, 10, 16, and 71 were rejected under 35 U.S.C. § 102(b) as being anticipated by Varma et al. The Examiner contends that Varma teaches an alternative oxidant source for cellular respiration, namely acetate. Specifically, the Examiner cites Varma pp. 3730, col. 2, paragraph 4; however, while this paragraph states that acetate is reconsumed in the presence of a glucose feed, it does not state that the uptake is for use as an alternative oxidant. To the contrary, it says that “[i]t is generally assumed that the presence of glucose represses the utilization of

other substrates. In contrast, we observed [...] that a sufficiently high cell density can result in the simultaneous consumption of glucose and acetate". In Varma's own words, acetate is another "substrate". Accordingly, Varma does not teach acetate as an alternative oxidant and thus cannot anticipate the present invention. But the analysis need not end here.

The data of Varma offers further evidence in support of acetate being taught as a substrate rather than an oxidant. Convincingly, Varma's data shows that the effect of a low glucose feed rate under aerobic conditions is an initial accumulation of acetate followed by a decline to essentially nothing. If acetate were an alternative oxidant source then it would continue to accumulate under aerobic conditions, rather than accumulate and then drop to zero. To the contrary, if acetate is a carbon source then it should not accumulate, which is consistent with the data. Further, the data includes results that show the accumulation and reuptake of acetate under anaerobic conditions. Acetate accumulates at low cell densities and continues to rise. If acetate is used as an alternative oxidant source then acetate should not accumulate in the absence of oxygen, rather it should be metabolized. Therefore, Varma cannot anticipate the present invention because acetate cannot be characterized as an alternative oxidant source.

The Examiner has also rejected claims 1-4, 6, 10, 13, 15, 17-20, 22, 27-29, 31-34, and 71 under 35 U.S.C. § 102(b) as being anticipated by Giani et al. Specifically, the Examiner contends that we have not established with sufficient evidence that the amount of alternative oxidant provided is insufficient for cellular respiration. The Applicant chooses to amend Claims 1 and 71 to add a further limitation to the aeration element, which has support in the specification but cannot be found in Giani. Specifically, both claims now include the limitation that the process includes aeration at a maximum oxygen replenishment rate. Giani does not teach the use of a maximum oxygen replenishment rate. To the contrary Giani teaches an aeration rate that depends on factors including fermenter geometry, stirrer geometry, energy input and whether the cell culture is in a growth or production phase. Therefore, Giani can no longer be said to anticipate the present invention.

The Examiner has rejected claim 71 for its preamble, which states a "defined medium" that is not used in the claimed process. We therefore amend Claim 71 by striking the word "defined" from the preamble.

The Examiner has rejected claims 1-4, 6-34, and 71 under 35 U.S.C. § 103(a) as being unpatentable over Giani taken in combination with Brock and Wagner. However, as noted above, Giani fails to teach a maximum oxygen replenishment rate, and Brock and Wagner do not fill in this gap. Accordingly, the foregoing references do not support a valid § 103(a) rejection.

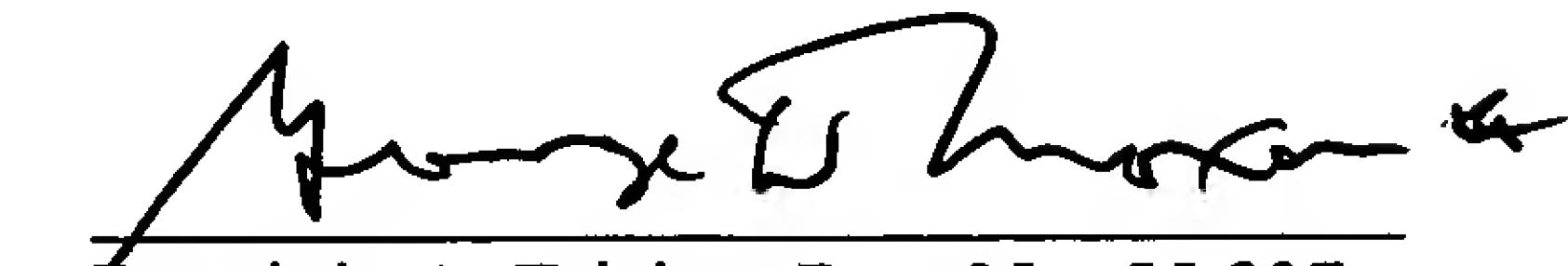
The Examiner has leveled a new rejection to claims 1-4, 6-34, and 71 under 35 U.S.C. §103(a) as being unpatentable over Wendt in view of Brock and Wagner. Specifically, the Examiner contends that Wendt and Brock sufficiently teach the alternative oxidant. The Examiner relies on Wendt to teach simultaneous aerobic and anaerobic respiration processes as claimed by the Applicant in Claim 1. However, Wendt discloses a process that is either fully aerobic or fully anaerobic. In fact, Wendt is ideally practiced under conditions where the anaerobic portion of the process is entirely devoid of any aerobic processes whatsoever because such processes tend to produce nitrates, and the primary objective of Wendt is to remove nitrates. Thus, Wendt does not teach a simultaneously aerobic and anaerobic process. To the contrary, it teaches away from a simultaneous process. Accordingly, the combination of Wendt, Brock and Wagner cannot teach every element of the claimed invention and thus does not constitute the basis of a viable § 103(a) rejection.

In addition to the foregoing amendments, the applicant makes further amendments sua sponte. In claims 1 and 71 the word “supply” has been deleted and replaced with the word “replenishment” to clarify that the element is directed to the rate of replenishing oxygen rather than the gas flow or other related rate.

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Should the Examiner wish to discuss any of the foregoing in more detail, the undersigned attorney would welcome a telephone call.

Respectfully submitted,



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